FLEXO USER MANUAL

Sleep Apnea Breathing Therapy Device

ENGLISH

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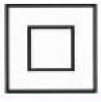
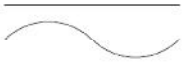
SYMBOL KEY

Symbol	Description
	Attention! Consult accompanying documents
	Type B applied part
IPX1	Protection against water
	Class II Double insulated
	Direct and alternating current supply

CAUTIONS AND WARNINGS!

CAUTIONS

- This device is restricted to sale by or on the order of a physician.
- Do not use the device before the recommended therapeutic pressure is prescribed by a physician.
- To prevent water entering the breathing circuit connection on the mask, the device must always be positioned below the head.
- Do not use the device at room temperatures above 35°C. If the device is used when temperature is above 35°C then the temperature of the airflow may exceed 41°C, which could cause thermal irritation or injury to the patient's airway.
- Do not place the device near any items (curtains, bedding, couch) or heating devices (air conditioners, radiators, vents) that may disrupt the airflow around the device.
- Before carrying or packing the device you must empty the humidifier of water
- Check the alarm function regularly, and if the device has not been used for a long time please check the power failure alarm before use. If the Power failure alarm does not work contact your dealer.
- If the clock needs to be reset, keep the Flexo switched on for 12 hours to ensure the clock and alarms are set.
- The date and time will also need to be reset of the device has not been in use for a long time.
- If the device has recently been placed in a very hot or very cold environment, wait for 2 hours to allow temperature to normalize before switching the device on.
- The device can only be operated at temperatures between 5°C and 35°C.

WARNINGS!

- The device cannot be used while mobile.
- This device is for adult use only and not for use by children or persons with certain disabilities who would require supervision in order to use the device safely.
- The device cannot be used for life support.
- Do not use the device in the presence of nitrous oxide or flammable anesthetic mixtures in combination with oxygen or air.

- In the event that the device noise level becomes higher than normal, the devices output of air becomes too hot, the device has an abnormal smell or if any part of the device becomes broken, stop using it immediately contact an authorized dealer.
- The device can only be switched off completely when the power supply is disconnected from the wall socket.
- Make sure the exhalation opening in the mask or swivel is open so that the exhaled air containing CO_2 can escape.
- To avoid rebreathing do not wear the mask for more than 3 minutes when the device is not switched on. (Note. At low pressures, the airflow may not be sufficient to remove all exhaled gas (CO_2) therefore some rebreathing may occur.)
- The air inlet of the device should never be covered.
- To avoid electric shock:
    - Do not use the device if the device casing or cables are damaged.
    - Do not use the device if it has been dropped in water.
    - Keep device away from water.
    - Before cleaning the device, pull the power plug out of the socket.
- If the patient experiences mucous membrane dryness in the nose and pharynx, frontal sinus trouble, earache, a running nose or skin sensitivity etc. you should consult your physician immediately.
- Operation of the device may be adversely affected by:
    - Electromagnetic fields exceeding the level of 3V/m in the test conditions of EN 60601-1-2
    - The operation of high frequency (diathermy) equipment.
    - Defibrillators, or short wave therapy equipment
    - Radiation (e.g., X-ray, CT)
    - Magnetic fields (e.g., MRI).
    - Do not sterilize the device with high pressured steam

LIABILITY

The manufacturer shall not be held liable for any damages in case of:

- Tampering, modifying, adding expansion features or repair by persons who have not been authorized by the manufacturer.
- Using accessory or spare parts that are not recommended by us, or not officially registered.
- Using the device in a way that was not instructed in the manual.

INTRODUCTION

INTENDED USE

Flexo respiratory sleep apnea breathing therapy device is used for treating obstructive sleep apnea or provide non-invasive ventilation in adult patients (>30 kg) for the treatment of respiratory insufficiency (a condition in which the patient can maintain ventilation without mechanical support for some period of time) or obstructive sleep apnea. It provides a stable continupus positive airway pressure. The therapeutic pressure is prescribed by a physician according to patients's condition.

It provides a stable continuous bi-level positive airway pressure.

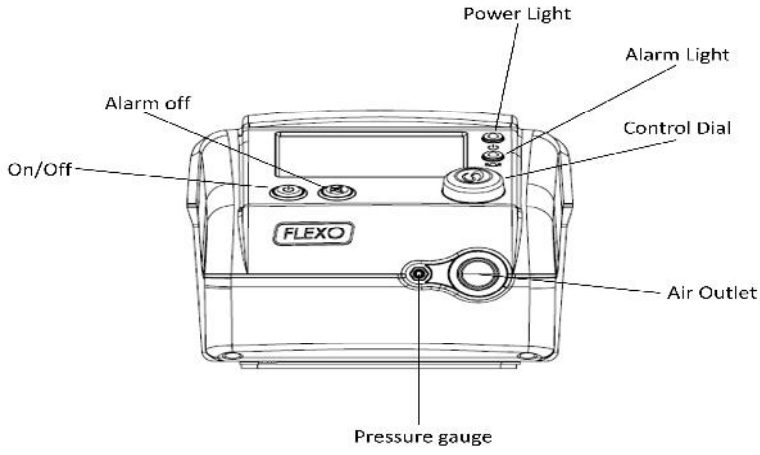
CONTRAINDICATIONS

The use of positive airway pressure may be contraindicated if the patient suffers from the following pre existing conditions:

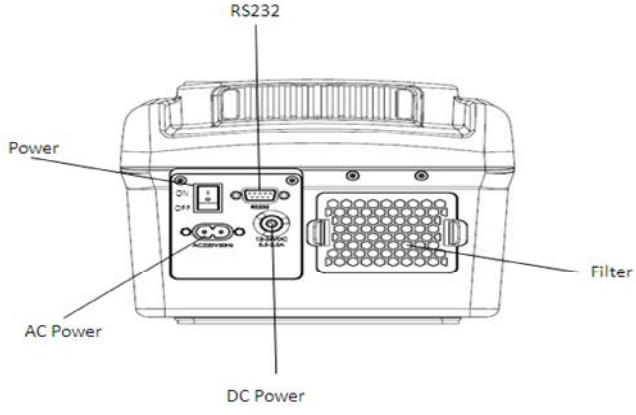
- Pneumothorax
- Pneumomediastinum (Air in mediastinum)
- Cerebrospinal fluid leakage
- Pneumocephalus
- Extremely low blood pressure or shock
- Confusion or coma resulting in the patient not been able to co-operate with or accept the mask
- Excessive secretions in the airway as well as not coughing effectively and weak voluntary breathing.

DESCRIPTION OF THE DEVICE

FRONT



BACK



Attention! The data transmission interface is only used during production or service when transmitting data to RS232 or the USB of a PC.

Equipment connected to the analog or digital interfaces must comply with the respective IEC standards (e.g. IEC 950 for data processing equipment and IEC 60601-1 for medical equipment). All configurations shall comply with the current version of the standard for SYSTEMS IEC 601-1-1. If you are in doubt consult the technical service department or your local representative. RS232 and the USB port are only for technical use.

FLEXO, ACCESSORIES AND PARTS

- 1 Flexo
- 1 Power cord
- Filter
- 1 Hose with and pressure tube

CONNECTING THE SYSTEM

- Check whether the device is damaged and if any accessories or parts are missing.
- Put the device on a stable and even surface. Make sure the air inlet in the back of the device is not blocked.
- Connect the power supply cord to the device.
- Connect the two ends of the hose to the device’s air outlet and mask separately.
- Connect the pressure tube to the pressure gauge in the device.
- Connect to the power supply.

PARAMETERS, OPERATION AND DISPLAY

PARAMETERS

Function	Introduction	Range/Measurement
IPAP	Inspiratory Positive Air Pressure	4 to 30cmH_2O with ST30 [0.5 cmH_2O per step
EPAP	Expiratory Positive Air Pressure	4 to 20cmH_2O [0.5 cmH_2O per step]
CPAP	Continuous Positive Air Pressure	4 to 20cmH_2O [0.5 cmH_2O per step]
VT	Tidal Volume	
BPM	Breaths per minute	4 to 60, 1bpm per step
MV	Minute Ventilation	Litres
IT	Inspiration Time	10~80% (1 % per change)
Leak	Leakage Volume per minute	
I-SLOP	Speed of rising pressure	1 to 6, 1 per step
I-SENS	Sensitivity of inspiration triggering	1 to 6, 1 per step
E-SENS	Sensitivity of expiration triggering	1 to 6, 1 per step
MODE	Operation mode	APCV, S, T, ST, CPAP
IE%	The percentage of inspiration time in a respiration cycle, applicable with T or ST mode	10% to 80% - 1% per step
RAMP	Ramp Time	0 to 60min, 1min per step
LowMV	Low minute ventilation alarm	1 to 10 L/m, 1 L/m per step (ON/OFF)
LowVT	Low tidal volume alarm	50 to 500 ml, 50 ml per step (ON/OFF)
Power Alarm	Power Failure Alarm	ON/OFF
HiPRES	High pressure alarm	ON/OFF
APNEA	Apnea alarm	10s to 40S, 5S per step (ON/OFF)

OPERATING THE DEVICE

BASICS

1. Plug the device into a power source.
2. Turn the device onto standby using the switch at the back of the device.
3. The Power light on the device will display green when the Flexo is on.
4. When the device is on standby the monitor display is visible.
5. Adjust the settings of the device according to the patient's requirements using the blue dial.

MAIN

In the bottom right corner of the monitor display, you can enter the main menu, which gives you three options.

- Monitor
- Alarm
- Default

MONITOR DISPLAY

The monitor display allows you to set the treatment options for the patients and to monitor the parameters as shown in the table below:

VT	MV	RR	IT	LK	MINIT	TVV
Tidal Volume	**Minute Volume**	**Respiratory Rate**	**Inspiratory Time**	**Leak**	**Minimum inspiratory time**	**Target Tidal Volume**

MODE

To set the treatment option the mode needs to be set, followed by the specific settings for that mode.

SPONTANEOUS MODE: S MODE

MODE：S	
IPAP	10.0
EPAP	4.0
ISLP	3
ISNS	3
ESNS	3

The inspiration and expiration phase is dependent on patient's spontaneous breathing. During the inspiration phase the device delivers at the preset IPAP pressure and during expiration phase the device delivers at the preset EPAP pressure.

TIMED MODE: T MODE

MODE： T	
IPAP	**10.0**
EPAP	**4.0**
BPM	**15**
I/T%	**36**
ISLP	**3**

The inspiration and expiration phase is dependent on the settings of the device. The patients breathing will be controlled by the BPM (Breaths per minute) and IE% (percentage of inspiration time over a respiration cycle) set

The pressure will be switched automatically at a rate determined by BPM and IE%.

CPAP MODE

MODE： CPAP	
CPAP	10.0
RAMP	0 min

In CPAP mode the device will output the set pressure constantly.

ST MODE / SPONTANEOUS-TIMED MODE

MODE： ST	
IPAP	10.0
EPAP	4.0
BPM	15
I/T%	36
ISLP	3
ISNS	3
ESNS	3

ST mode includes 2 patterns, when the patient is able to breathe spontaneously, the device works as S mode; however, when the patient is unable to breathe spontaneously or the patient's breath slows to a rate less than the preset backup rate (BPM), the device will switch to T mode.

PRESSURE CONTROL MODE: APCV (ASSISTED PRESSURE CONTROL VENTILATION)

MODE： APCV	
IPAP	10.0
EPAP	4.0
BPM	15
I/T%	36
ISLP	3
ISNS	3
ESNS	3

APCV mode is similar to the ST mode, except that all breaths in a controlled cycle. The APCV mode is a pressure-limited, device-or-patient triggered, time-cycled mode. Therefore, the inspiratory pressure may be triggered by the patient or by the therapy device, but IPAP will be pressure-limited with a set cycle time determined by the inspiratory time control (IE %)

ALARM

To set an alarm use the blue dial to select which alarm is used and then turn ON or OFF

ALARM SET		
HIGH IP		ON/OFF
APNEA	10	ON/OFF
LOW VT	100	ON/OFF
LOW MV	4	ON/OFF
HIGH LEAK	50	ON/OFF
LOW LEAK	10	ON/OFF
YES		NO

APENA ALARM (APENA)

The apnea alarm detects pauses in spontaneous breathing. The alarm is activated when the time between spontaneous breaths exceeds the Apnea alarm setting. The alarm setting range is from 5s to 60S, 5S per step.

The alarm is terminated when two consecutive spontaneous breaths occur within the apnea alarm time setting or by pressing the Alarm key.

LOW TIDAL VOLUME ALARM (LOWVT)

The low tidal volume alarm is activated when the calculated tidal volume ≤ the alarm setting. The alarm setting range is from 50 to 500 ml, 50 ml per step.

The alarm is terminated when the calculated tidal volume > the alarm setting or press the Alarm key.

LOW MINUTE VENTILATION ALARM (LOWMV)

The low minute ventilation alarm detects when a user is not receiving the specified volume of air per minute. The alarm is activated when the calculated minute ventilation ≤ the alarm setting. The alarm setting range is from 1 to 10 L/m, 1 L/m per step.

The alarm is terminated when the calculated minute ventilation > the alarm setting or by pressing the Alarm key.

HIGH PRESSURE ALARM (HIPRES)

The high-pressure alarm limits the high pressure to the patient by activated the alarm when the pressure is at too greater level. The alarm is detected when the IPAP ≥ 30 cmH_2O.

The alarm is terminated when the IPAP < 30 cmH_2O.

HIGH LEAKAGE

Alarm for High Leakage

LOW LEAKAGE

Alarm for Low leakage

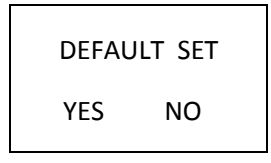
CHECKING THE POWER FAILURE ALARM

Switch the device on and keep running for at least 10 seconds. If the power cord is unplugged or the power is switched off at the socket the alarm should sound. Check whether the alarm lasts long enough (around 30sec). When the device is switched on the alarm should stop automatically. Please check the alarm at least once a month.

DEFAULT

You can return the Flexo to the default setting through the Main menu.

Use the blue dial to select YES or NO.



FUNCTIONS OF THE DEVICE

INSPIRATORY TIME PERCENTAGE SETTING

Inspiratory time percentage of the total respiratory cycle as inspiratory ratio.

When the Flexo is in T, ST or APCV mode the inspiratory ratio can be set. The range can be set between between 10 to 80%, adjusted in intervals of 1%.

RESPIRATORY RATE (BPM)

When treatment for work in T, ST or APCV mode, the frequency can be set. Frequency setting range of 5 to 40 times / minute, adjusting interval 1bpm

RAMP

When this function is selected the device will start delivering the minimum air pressure first before increasing the pressure steadily to the set pressure within the set time. This function is to allow the patient to fall asleep more comfortably. This soft start function is particularly helpful for patients who are not accustomed to continuous positive airway pressure therapy. The pressure delay time range is between 0 - 60 minutes with pressure steps every minute.

AUTOMATIC MODE

In the CPAP mode, if "Automatic" (ON) mode is selected then when the mask is breathed into the Flexo will automatically begin to provide therapy. When you remove the mask within 15 seconds, the Flexo will automatically shut down. In this mode, if the breathing tube or breathing mask are disconnected the Flexo will automatically shut down.

CLEANING AND MAINTENANCE

CLEANING THE FLEXO

WARNING! To avoid electrical shock unplug the Flexo power cord before cleaning the device

WARNING! Do not immerse the device in liquid or allow any liquid to enter the enclosure, inlet filter, or any other openings

1. To clean the exterior of the device use a dampened cloth and a mild detergent. Allow the device to dry completely before plugging in the power cord.
2. The mask and tubing should be cleaned daily. For details on cleaning your mask and accessories refer to the cleaning instructions packaged with the accessories.

CHANGING FILTER

The fine filter is in the filter cassette at the back of the device. Take it out and change it with a new one every week. Never use the device without a filter.

Dirty inlet filters may cause high operating temperatures that may affect device performance. Regularly examine the inlet filters for cleanliness. If there is a lot of dust or smoke in the environment change the filter more frequently.

Ensure that you buy your filters from a vendor endorsed by the manufacturer.

WARNING! Ensure the filter is dry. A damp or wet filter may damage the device.

WARNING! Ensure the device is powered off before changing the filter.

TROUBLESHOOTING

- Different problems that may be encountered, their causes and solutions are detailed below.
- If your dealer cannot resolve the problems, please consult your physician or contact our service center.

Problem	Cause	Solution
Low output pressure	Air leak is detected by the device.	Dry thoroughly or clean the pressure tube.
		Check all connections to reduce leakage. Re-seat mask and adjust headgear to reduce leakage around mask.
Discomfort due to high pressure.	When pressure is over 13cmH_2O(~1.3kPa), some patients will feel discomfort. However, this pressure may be needed for effective therapy.	You may take up to 4 weeks to be accustomed to higher pressures. When using the device, breathe through nose with mouth closed and keep calm. If you continue to experience discomfort consult your physician.
Symptoms of sleep apnea syndrome appears again. (like day time sleepiness)	When your weight is increased, your nose is blocked or you drink etc, you need higher pressures.	Consult your physician.
Air is too warm	Dirty filter	Change filter
	Air inlet blocked	Check air inlet
	The device is too close to wall, curtains or other objects, which hinders air circulation	Take away the device to keep it over 20cm from wall, curtains or other objects
No air flow	Defective device	Contact our service center
	Water in the pressure tube	Dry the pressure tube thoroughly

Problem	Cause	Solution
Low air flow	Ramp function is active	Decrease soft start time
	Air inlet blocked	Check air inlet
Motor always operates at maximum speed	The pressure tube is not connected or it is blocked	Check the pressure tube
	Leakage in the device	Contact our service center
When turned on, the device doesn't work	The device is in automatic operation (AUTO ON)	Set the device to manual operation (AUTO OFF)
	Power is not plugged in	Check whether power cable is connected with the device
	No electric supply	Check main electricity supply,
	Fuse is blown (Note: before checking, unplug power cable)	Change fuse Contact our service center
Motor works normally but the output pressure is lower than the set pressure	Patient hose or pressure tube is not correctly connected with the device	Check whether connection is correct and firm
	Air leakage through mask or patient tube	Contact our service center
Only low output pressure	Dirty filter or air outlet blocked	Change filter, check air outlet
	Therapeutic pressure readjusted	Consult your physician
	Soft start function active	If necessary, cancel soft start function or set soft start function time again
Too noisy	Patient hose is not connected or connected incorrectly	Check connection
	Leakage through mask or patient hose	Check patient hose
	Not air tight between humidifier and device	Check humidifier and device
Date and time invalid	The device not used for long time (at least three months)	Put the device on stand-by mode for 12 hours.

SERVICE

- Service of the Flexo should only be performed by persons authorized by the company.
- To increase the device's life, the user must read the Flexo's safety instructions and cleaning instructions.

SPECIFICATIONS

Flexo	
Pressure range	ST30 - 4cm H_2O (~0.4kPa) -30 cm H_2O (~2.0kPa)
Pressure variance	±0.4 cm H_2O (~0.04kPa)
Ramp time	0-60min. adjustable 1min./step
Noise: (10 cm H_2O/~1.0kPa)	<50dB (A)
Dimensions	300mm(L)×200mm(H)×170mm(W)
Weight	2.75Kg
Water temperature	44°C Maximum
AC power	AC Input 100-240V 2-1A 50-60Hz
DC power	DC Input 12-24V 5.5-2.5A
Protection again electric shock	Class II
Degree of protection against electric shock	Type B Applied Part
Degree of protection against harmful ingress of water	Ordinary Equipment, IPX1
Electromagnetic Compatibility	Flexo device meets the requirements of EN 60601-1-2.

Operation	
Temperature	+5°C ～ +35°C
Relative humidity	10%％～ 93%(non-condensing)
Atmosphere pressure	700hPa ～ 1060hPa

Transport or storage	
Temperature	-20°C ～ +55°C
Relative humidity	10% ～ 93%(non-condensing)
Atmosphere pressure	500hPa ～ 1060hPa

DISPOSAL

This device, its accessories and its packaging have to be disposed correctly at the end of the usage. Please follow Local Laws or Regulations for disposal.

ELECTRIC MAGNETIC INFORMATION

GUIDANCE AND MANUFACTURERS DECLARATION OF ELECTROMAGNETIC IMMUNITY FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE SUPPORTING

Attention! Please use Flexo Sleep apnea breathing therapy device according to electric magnetic information in list.

The Flexo is intended for use in the electromagnetic environment specified below. The user of the Flexo should ensure that it is used in such an environment.

Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Flexo uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The Flexo is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±4 kV air ±8 kV air	±6 KV contact ±4 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flexo requires continued operation during power mains interruptions, it is recommended that the Flexo be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) Magnetic field IEC-61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at normal levels typical of a location in a commercial or hospital environment.
NOTE: UT is the A/C mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment including cables should not be used close to any part of the Flexo other than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location where the Flexo is used exceeds the applicable RF compliance level above, the Flexo should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as, re-adjusting or relocating the Flexo. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE FLEXO

The Flexo is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.
The customer or the user of the Flexo can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Flexo as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter (W)	Separation distance according to the frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.39	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

CONTACT DETAILS

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